



## Federal Aquaculture Regulatory Fact Sheet Series



# HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION OFFICE OF FOODS AND VETERINARY MEDICINE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

<http://www.fda.gov/Food/default.htm>

### **Regulatory Subject Area: Seafood Safety**

The FDA operates a mandatory safety program for all domestic and imported fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, and pertinent regulations. The FDA program includes research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance. The following are the key components for imported and domestic seafood safety at FDA.

- **Food Safety Modernization Act of 2011**

FDA conducts its seafood safety oversight activities in conformance with its statutory authorities, which have been expanded by the Food Safety Modernization Act (FSMA). FSMA represents the first major overhaul of FDA's food safety law in more than 70 years and is transforming FDA's food safety program. FSMA closes significant and longstanding gaps in FDA's food safety authority, with new safeguards to prevent, rather than react, to food safety problems, and gives FDA important new tools to ensure that imported food is as safe as domestic food.

The major elements of the law can be divided into five key areas:

- Preventive controls,
- Inspection and compliance,
- Imported food safety to ensure that imported foods meet US standards and are safe for our consumers,
- Response and mandatory recall authority for all food products
- Enhanced partnership and collaboration among all food safety agencies

Rules and Guidance for Industry related to the FDA Food Safety Modernization Act (FSMA) can be accessed at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

- **Bioterrorism Act of 2002**

Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") was signed into the law on June 12, 2002. Among other things, the Act covers the following four provisions:

- Section 305 (Registration of Food Facilities) - requires the owner, operator, or agent in charge of a domestic or foreign facility to register with the FDA;
- Section 306 (Establishment and Maintenance of Records)- requires the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, (i.e., one up, one down);
- Section 307 (Prior Notice of Imported Food Shipments) - requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry;
- Section 303 (Administrative Detention) - FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. This will further help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/default.htm>

- **Hazard Analysis and Critical Control Points**

A HACCP program is a preventive control system which addresses food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution and consumption of the finished product. The HACCP regulation for Fish and Fishery Products is published in 21 Title of Code of Federal Regulations Part 123.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=123>

FDA provides guidance documents and regulatory information to facilitate the food industry compliance with the US laws and regulations. The 4<sup>th</sup> edition of Fish and Fishery Products Hazards and Controls Guidance published in April 2011 is intended to assist processors of fish and fishery products in the development of their HACCP program.

The 2<sup>nd</sup> edition of Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins (the Bad Bug Book) provides current information about the major known agents that cause foodborne illness.

<http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/default.htm>

- **International Collaboration and Outreach**

The volume and variety of foods imported into and exported from the United States has increased dramatically in recent years. FDA and CFSAN work globally to better accomplish its domestic mission to promote and protect the public health of the United States and to ensure food safety and public health measures are not compromised in international and bilateral trade forum. FDA has developed new strategies and assumed more responsibilities related to global food safety.

In pursuit of appropriate international collaborations, FDA utilizes a wide variety of international arrangements, such as confidentiality commitments and memoranda of understanding and other cooperative arrangements. FDA has also strengthened and better coordinated its international engagements by establishing permanent FDA posts abroad in strategic locations in Asia, Latin America, Europe and Middle East. The posting of FDA staff in certain overseas regions is a key part of the agency's strategy for expanding oversight of imported food.

CFSAN conducts outreach and provides technical assistance on its laws, regulations, and policies to foreign governments, industry, and the global public health community to enhance international understanding of food and cosmetic safety to protect consumer health. Information is disseminated through lectures in conferences, consultations, exchange of information with foreign visitors, proactive training seminars, training videos, Internet programs, and technical cooperation activities.

<http://www.fda.gov/Food/InternationalInteragencyCoordination/default.htm>

- **Foreign Food Facility Inspection Program**

FDA has increased the number of routine inspections worldwide of foreign food facilities including processors of fish and fishery products that export to the United States. This increase is mandated by new requirements under the FDA Food Safety Modernization Act (FSMA). The inspections are design to:

- Identify potential food safety problems before products arrive in the United States
- Determine the compliance status of facilities to FDA's requirements and food safety standards
- Help the agency make admissibility decisions when food products are offered for importation into the United States
- Help ensure that food products under FDA's jurisdiction meet U.S. requirements

<http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm196386.htm>

- **Domestic Federal and State Agreements and Coordination**

FDA and CFSAN have in place multiple agreements with other U.S. government agencies to ensure clarity of jurisdiction and responsibilities and better interagency coordination on foodborne

illnesses. For example, FDA and the [National Marine Fisheries Service's](#) (NMFS) Seafood Inspection Program have certain common and related objectives in carrying out their respective regulatory and service activities that lend themselves to cooperation under a [Memorandum of Understanding](#) (MOU) that sets forth the working arrangements between the agencies that facilitate each agency's efforts to discharge its responsibilities related to the inspection of fish and fishery products.

<http://www.fda.gov/Food/InternationalInteragencyCoordination/DomesticInteragencyAgreements/default.htm>

- **Monitoring Programs**

The FDA surveillance monitoring programs provide coverage of domestic and imported fish and fishery products to ensure a safe and wholesome seafood supply for the US market. The programs routinely test for microbiological contamination, parasites, decomposition, chemical contaminants, marine toxins, food and color additives, filth, veterinary drug residues, labeling. The programs also provide direction to the field for developing inspectional priorities and instructions specific to the inspection of seafood processing facilities and products.

FSMA directs FDA to establish a program for testing of food by accredited laboratories and will require that food be tested by accredited laboratories in some circumstances, such as in support of admission of imported food under Detention Without Physical Examination (also known as Import Alert). FDA is developing the laboratory accreditation program as part of its FSMA implementation efforts.

<http://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/default.htm>

- **PREDICT**

The Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, is a new FDA electronic screening system for imports, which allows FDA to focus its resources on the most likely threats to public health. PREDICT assists FDA in targeting higher-risk shipments for examination. It also expedites the clearance of lower-risk shipments, but only if accurate and complete data are provided by importers and entry filers. PREDICT will improve the agency's ability to detect trends and investigate patterns. This, in turn, will help to make more efficient use of FDA's import resources and allow FDA to adjust import sampling levels for seafood products over time and as appropriate.

<http://www.fda.gov/ForIndustry/ImportProgram/ucm172743.htm>

- **Integrated Food Safety System**

FDA collaborates with the [President's Food Safety Working Group](#) to modernize food safety by building collaborative partnerships with consumers, industry and regulatory partners.

- **Consumer Information**

The government-wide FoodSafety.gov web site ( <http://www.foodsafety.gov/>) provides a widget that displays the latest recalls and food safety alerts from both FDA and USDA.

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